

Reproductive Care Center

Informed Consent for Cryopreservation, Storage and the Disposition of Human Embryos

I. General Information: (Please Read Carefully)

Purpose of Cryopreservation

The purpose of cryopreservation in an Assisted Reproductive Technology (ART) program is to preserve surplus embryos, not replaced during the initial transfer procedure, for replacement at a later time. This procedure can be beneficial by eliminating the need for another ovarian stimulation and egg aspiration procedure when the initial in-vitro fertilization (IVF) fresh cycle (or frozen egg cycle) does not result in a pregnancy, or when additional pregnancy(s) are desired at a later time. The option of freezing embryos eliminates consideration of transferring too many embryos with high risk of multiple births or discarding embryos that might have become healthy babies.

Background on Cryopreservation

Reproductive Care Center (RCC) usually freezes 1-4 embryo(s) in cryo straws. Freezing embryos in groups minimizes the work and expense while usually allowing for the thaw of the appropriate number of desired embryos for transfer. During a frozen embryo transfer (FET) cycle, RCC thaws the best combination of frozen embryo groups in order to obtain the desired number of intact embryos for transfer.

If desired, Reproductive Care Center (RCC) can freeze each embryo individually (extra charge) in cryo straws. During a frozen embryo transfer (FET) cycle, RCC can serially thaw only the exact number of embryos necessary for your transfer. This practice may maximize the number of possible transfers from your retrieval cycle but adds additional time and cost to the procedure.

Embryos may survive the freeze-thaw process completely intact with all the cells (blastomeres) alive and healthy. However, most embryos lose one or more cells in the process. If at least 50% of the cells survive the thaw, we designate the embryo as surviving (intact). When less than 50% of the cells survive, we designate the embryo as partially surviving. All surviving embryos yield reasonable implantation rates, although the completely surviving embryos yield the highest implantation rates. Partially surviving embryos uncommonly lead to a successful pregnancy but because they occasionally do implant, we allow transfer of these embryos if the patient desires.

The success rate from FET cycles is less than from transfer of fresh embryos (embryos that have not been frozen yet). The overall success rate depends on the age of the woman when the embryos were formed, the embryo quality score, the status of the embryo at thaw and any other factor that would otherwise influence IVF success. Recent success rates from FET are available on our website (www.fertilitydr.com), through information submitted to the Society for Assisted Reproduction (SART – www.SART.org), the CDC (www.CDC.gov) and through discussion with your RCC physician.

We understand that available human data as well as animal data do not suggest that embryo freezing increases the risks of congenital anomalies (birth defects) in the resultant offspring. Although the risk of birth defects from frozen human embryos is similar to natural conceptions, RCC cannot guarantee a normal birth. The expected rate of major birth defects in the normal population is 3-4%.

Prior to cryopreservation of embryo(s), and in compliance with the American Association of Tissue Banks, and RCC policies and procedures, the husband and wife are required to provide evidence of negative blood tests for Hepatitis B Surface Antigen, Hepatitis C antibody, HIV-1 & 2 antibody, syphilis, and gonorrhea and chlamydia within 24 months of the anticipated egg retrieval.

Risks to the Husband and Wife

While there are no known risks to the Husband or Wife from the cryopreservation procedure itself, when a thawed embryo(s) are placed in the uterus, the risks to the wife are the same as for a regular fresh IVF transfer, including but not limited to: infection, cramping, bleeding, ectopic pregnancy, miscarriage, multiple birth, and failure to achieve pregnancy.

Risks to the Embryo

Currently, 50%-70% of the embryos are anticipated to survive the freezing and thawing procedures. During the freezing and thawing process, it is possible that cell trauma or death of embryos could result from loss during normal handling, freezing, maintenance, storage, withdrawal, thawing, movement in the lab or between labs, malfunction of equipment, human error, natural disaster, or acts of a public enemy. Back-up systems are in place to decrease the likelihood of mechanical failure and malfunction, but circumstances beyond our control could develop and result in the loss or death of embryos. It is not known how long embryos can be stored without death or decreased viability, but you are encouraged to make early use of them.

Reproductive Care Center

II. Informed Consent for the Cryopreservation of Human Embryos

We, the undersigned Husband and Wife are legally married and agree to participate in the Reproductive Care Center's in vitro fertilization and embryo cryopreservation and storage program. We are, by this document, granting permission for one or more of our embryos to be frozen. We realize that there is no guarantee that any embryo(s) will be available for freezing or will survive the freezing or thawing process.

- (1) In the event that our embryos are initially assessed as unlikely to survive cryopreservation, we understand that it is the policy of the RCC to further culture such embryos. After additional culture, viability will be assessed. Those embryos considered to be viable may be cryopreserved at the later developmental stage (Blastocyst). If assessed as non-viable (either initially or after extended culture), we give consent for the RCC to discard such embryos.
- (2) We agree that prior to the RCC thawing any cryopreserved embryos for transfer thereof to the Wife, BOTH the Husband AND the Wife must sign a separate written consent (Informed Consent for Frozen Embryo Transfer) in the presence of the RCC (or notary public), expressly requesting and authorizing the thawing and transfer for each attempt at achieving pregnancy.
- (3) We understand that the policy of the RCC is not to transfer any embryos into (1) unmarried women, (2) women over the age of 50 (unless approved by RCC physicians after review), or (3) women who cannot safely carry a pregnancy according to the judgment of the physician transferring the embryos. Women who cannot safely carry a pregnancy could elect to use a gestational surrogate if desired.
- (4) The 1992 Fertility Clinic Success Rate and Certification Act requires the Centers for Disease Control and Prevention (CDC) to collect cycle-specific data as well as pregnancy outcome on all assisted reproductive technology cycles performed in the United States each year and requires them to report success rates using these data. Consequently, data from our IVF procedure with the use of frozen eggs will be provided to the CDC, and to the Society of Assisted Reproductive Technologies (SART) of the American Society of Reproductive Medicine (ASRM). The CDC may request additional information from the treatment center or contact us directly for additional follow-up. Additionally, our information may be used and disclosed in accordance with HIPAA guidelines in order to perform research or quality control. All information used for research will be de-identified prior to publication. De-identification is a process intended to prevent the data associated with our treatment being used to identify us as individuals.
- (5) It is intended that the RCC IVF and cryopreservation program option operate indefinitely. However, if the cryopreservation program at the RCC facility discontinues or ceases to operate then one or both of the following options may be exercised at our expense:
 - a) Transfer of embryos into the wife before closure of the facility;
 - b) Transfer to another storage facility.

Under such circumstances, we can be notified by certified mail at our latest address on file at the RCC. If the notice is returned for insufficient address or similar reason, or if no written response thereto is received within 30 days after mailing, we understand that the embryos will be at the sole discretion of the RCC, including donation or disposal.

- (6) We understand if our embryo storage fees become delinquent for more than 90 days, we will be sent a certified letter to our latest address on file. If there is no response and payment is not received within thirty days, RCC shall have the legal right to dispose of our embryos.
- (7) We agree to keep our most current mailing address on file at the RCC at all times during our participation in the IVF Program, while the cryopreserved material is being stored by the RCC, and for 1 year thereafter. We will advise the RCC promptly upon each change of address or prolonged absence (greater than 90 days) from the last address on file. Unless and until superseded in writing, our mailing address is the address currently shown on all forms. In the event that the RCC changes its mailing address, the RCC shall provide the same by way of certified mail, to those who currently have cryopreserved embryos stored, prior to such change. If we fail to notify the RCC within 90 days of change of address, the RCC shall retain the legal right to dispose of our embryos.
- (8) If either one or both of us shall make the RCC (or any of its directors, officers, employees, or agents) or assigns, a party to any arbitration or litigation between the RCC and us, as to the rights of either or both of us to the stored frozen embryos, we shall be liable for the reasonable attorney's fees and other costs of the RCC including loss of time incurred by the RCC personnel in such litigation, unless the RCC is found therein to have: (i) breached this agreement, (ii) acted arbitrarily and capriciously so as to justify being made a party to the legal proceedings, or (iii) committed a legal wrong against the Husband and/or Wife.
- (9) We understand that if either one or both of us declares any kind of bankruptcy, that our embryos stored at the Reproductive Care Center may be disposed of once the prepaid storage has elapsed.

Reproductive Care Center

- (10) We understand that if we or any of our offspring should require any medical treatment as a result of physical injury thought to arise from our participation in this program, financial responsibility for such care will be our own, except for any matter involving gross negligence.

III. Pre-freeze Agreement for the Disposition of Cryopreserved Human Embryos

We accept responsibility for the ultimate disposition of the cryopreserved embryos. However, we understand that this input cannot be an absolute right but must be consistent with the interests of ethical medicine, and applicable law. We agree that the ultimate use or disposition of cryopreserved embryos is subject to applicable laws and court decisions that affect the legal status or control of embryos. Certain situations may arise that could alter the original intent of the IVF-Cryopreservation procedure, that is, our joint reproductive goal of bearing a child. If the original intent can no longer be fulfilled, then one of the options listed below, for the disposition of cryopreserved embryos, must become operational.

We understand that the cryopreserved material is subject to our joint disposition and that all decisions about its disposition must be joint decisions, except where specified below. We may change our election at any time before disposition by execution of a "Change of Disposition Letter", signed by BOTH of us, notarized and sent by certified mail. Notice is not effective until received by the RCC, as evidenced by the return receipt, and documentation by the director of the RCC. Said letter shall remain in full force and effect unless and until superseded. In the absence of mutual consent by both signatures, this agreement remains binding. If we undergo further IVF cycles at RCC, this agreement regarding the disposition of cryopreserved embryos will apply to any future IVF cycles for 5 years from the date of signing or for up to 12 IVF cycles.

Option 1: Grant custody of the embryo(s) to the other spouse for responsibility and control of disposition.

Option 2: Transfer custody of the embryo(s) to a third party agent (family member or close friend), designated by both of us, who will be responsible for embryo disposition as if they were the biologic parent. Such third party must accept such responsibility by signing a Transfer of Custody of Cryopreserved Embryos document, along with us, in the presence of an RCC witness or notary public. If option 2 is requested but the Transfer of Custody of Cryopreserved Embryos document is not completed then option 3 will automatically apply.

Option 3: Transfer custody of the embryo(s) to the RCC for anonymous donation to a needful married couple.

We understand that **if** we have indicated our willingness to donate our embryos, that we must fill out a questionnaire on our physical characteristics, education, and the health of ourselves and our families. We consent to undergo genetic screening in order to determine if genetic defects exist. We fully understand that this screening may require having our blood drawn for confirmation of negative tests for specific diseases.

We consent (if required) to undergo testing at an FDA approved laboratory for blood borne and sexually transmitted diseases such as, but not limited to, syphilis, Hepatitis B and C, CMV (cytomegalovirus), chlamydia, gonorrhea and Human Immunodeficiency virus (HIV). We fully understand that this would require us to have our blood drawn and urine samples obtained within 30 days prior to or 7 days after the egg retrieval and that a second test requiring an additional blood specimen for HIV may be required six months later.

We fully understand that if abnormalities are found in the genetic, laboratory or psychological screening, we may not be allowed to donate the embryos.

We fully understand that we will not be compensated for the donation of our embryos. We agree to rely upon the discretion of the physicians and staff at RCC in the selection of a qualified recipient couple. We fully understand that all information concerning the identity of the recipients of our embryos is confidential. We agree not to attempt to discover the identity of the recipients of our embryos now, or at any time in the future. We understand that the recipient couple(s) agree(s) not to attempt to discover the identity of the donor couple now, or at any time in the future.

To the extent permitted by law potential adoptive parents will not have any access to our identities, but will receive the information from the questionnaire to assist in making their decision. We understand that donation of our embryos will be anonymous.

We forever hereafter relinquish any claim to or jurisdiction over offspring that may result from transfer of our embryo(s) to another woman. We consent to give up all maternal and paternal rights and responsibilities to any child(ren) conceived through these donated embryos. We understand that in such an event that we have indicated our wish for our embryos to be donated, and either after reasonable time and efforts have been expended, no recipient can be found, or if applicable future laws prohibit donation of embryos, that our embryos will be discarded.

Reproductive Care Center

- Option 4:** Transfer custody of remaining cryopreserved embryos to the RCC for disposal.
- Option 5:** Transfer custody of remaining cryopreserved embryos to the RCC for medical research, laboratory training, quality control or disposal as deemed appropriate at the discretion of RCC.
- Option 6:** Grant custody to the wife for responsibility and control as to their use or disposition.
- Option 7:** Grant custody to the husband for responsibility and control as to their use or disposition.

As Husband and Wife, we jointly choose the indicated option for the following situations. (Please indicate one option for each situation by the **initials** and **date** of both Husband and Wife).

- (A) In the event of death, disability or legal incapacity of **one** of us, we hereby acknowledge and agree to:

Option # _____
(1 through 5) Husband Wife Date

- (B) In the event of death, disability or legal incapacity of **both** of us, we hereby acknowledge and agree to:

Option # _____
(2 through 5) Husband Wife Date

- (C) In the event of legal separation or divorce, we hereby acknowledge and agree to:

Option # _____
(2 through 7) Husband Wife Date

- (D) In the event that we decide not to use any stored embryos in an attempt to initiate a pregnancy we hereby agree to:

Option # _____
(2 through 7) Husband Wife Date

- (E) In the event there is a change in the physical condition of the Wife which renders her incapable of receiving a transfer or of carrying a pregnancy to term (including, but not limited to hysterectomy) and we are unwilling or unable to use a gestational surrogate we hereby acknowledge and agree to:

Option # _____
(2 through 7) Husband Wife Date

We understand that if the wife has a hysterectomy or a serious change in health, the only chance for pregnancy would be for a gestational surrogate to carry the pregnancy. We understand that RCC will help arrange for a gestational surrogate if needed or we can provide a gestational surrogate of our choosing that could be used after appropriate consultation and screening. We understand that the expenses related to the use of a gestational surrogate would be our responsibility.

- (F) In the event that this contract is breached due to: (a) lack of payment for due or upcoming services [see Section II, paragraph 7, 8 and 10], (b) lack of a response following certified notification by mail which requires action on disposition of frozen stored embryos [see Section II, paragraph 7], or (c) failure to maintain current address on file with the RCC [see Section II, paragraph 8], then we hereby agree that RCC may dispose of the embryos.

IV. Limits On Liability

We agree that RCC shall be liable for loss, injury or damage to our embryos only if such loss, injury or damage is directly caused by RCC's gross negligence in the performance of its duties. Furthermore, we agree that if RCC's gross negligence results in loss, injury or damage, RCC will only be liable for payment of Liquidated Damages as defined below. RCC will not be liable for punitive damages or consequential damages of any type, including but not limited to damages for mental, emotional, financial, consorsial, parental, societal injury and the like.

We agree with RCC that it would be impracticable and extremely difficult to fix actual damages for the loss, injury or damage of our embryos. In the event of loss, injury or damage to our embryos caused by RCC's gross negligence, liquidated damages shall be in the amount of Five Hundred Dollars (\$500) for each embryo, provided that RCC's total liability for loss, injury or damage to Patients' embryos shall not exceed Two Thousand Dollars (\$2,000) for all such embryos ("Liquidated Damages").

V. Agreement of Husband and Wife to Participate

We acknowledge that we have carefully read and fully understand this document. We have had the opportunity to ask any questions and have them answered to our satisfaction. We have been given the opportunity to discuss this document with our

Wife's Initials _____ / Husband's Initials _____

Reproductive Care Center

attorney. We voluntarily choose to participate. We understand that we may revoke our consent at any time prior to beginning the procedure and that our decision will not affect our relations with the RCC. By exercising the cryopreservation option, we accept the responsibilities, conditions and risks involved as set out in this document. In addition, we consent to the techniques and procedures required to attempt In Vitro Fertilization and Cryopreservation, embryo storage and a treatment cycle leading to a transfer of frozen thawed embryo(s). It is further expressly agreed that we hereby release the RCC and its personnel and medical staff from all responsibility and liability for the consequences, if any, resulting from participation in this procedure. We understand that all reasonable efforts to maintain confidentiality will be made, within the limits of billing, insurance and legal requirements.

Unless otherwise agreed to in writing, we agree that any possible dispute or claim in relation to services which we receive from RCC shall be settled solely by arbitration. Any arbitration proceeding will be conducted in accordance with the laws of the State of Utah. The locale will be Salt Lake County, Utah, and the arbitrators' judgment may be entered in any appropriate court and shall be binding and enforceable.

We acknowledge that neither the RCC nor its IVF team have made any warranties or representations with respect to: (I) the pre or post thaw viability of our embryos, (II) the successful establishment of pregnancy following uterine placement of our previously frozen embryos, (III) the lack of risk of a birth defect, miscarriage, tubal and/or ectopic pregnancy, multiple pregnancy, or pregnancy complication after embryo placement in the uterus or (IV) the infallibility of the liquid nitrogen-cooled storage refrigerators or any other IVF equipment or procedure.

We do hereby consent to having our embryos frozen and stored at the Reproductive Care Center for possible future use. There is a charge for embryo cryopreservation (freezing). If we desire that each embryo be frozen individually there is an additional charge above the basic freezing fee. These costs have been explained to us and we have received a copy of the current "IVF Financial Policy" document for review. **This freezing charge is applicable for each day that embryos are frozen.** The freezing charge is the same regardless of the number of embryos available for freezing on that particular day or the day of freezing (day 1-7). If embryos from the same cycle are frozen on separate days (such as day 3 cleavage embryos and day 5 blastocysts) then there will be a separate charge for each day embryos are cryopreserved.

We desire that our embryos be (select one):

_____ Frozen in groups

_____ Frozen individually

This selection (regarding freezing in groups or individually) will apply to any future IVF cycles with embryo cryopreservation for 5 years from the date of signing or for up to 12 IVF cycles unless we request a change in writing. We accept responsibility for the payment of fees to store the embryos. Storage fees are billed on an annual basis at the end of each calendar year for the upcoming year. We understand that if we fail to pay our storage fees within thirty days of a certified notice that such payments are due, our embryos may be discarded. We acknowledge that if either of us have a significant viral infectious disease, as determined by an RCC physician, that we may be required to store our embryos at another facility. There will be additional charges for shipping and separate outside facility storage fees in this situation.

We accept the potential risks and benefits of the freezing, storing, and thawing including failure of the embryos to survive the process or initiate a pregnancy.

Husband's Signature

Date

Witness to Husband's Signature

Date

Wife's Signature

Date

Witness to Wife's Signature

Date

Note: Please deliver this consent form to the office of the Reproductive Care Center, 10150 Petunia Way, Sandy, Utah 84092. We suggest that you keep a copy in your safety deposit box or another place in which you keep important documents and that, if you have a personal attorney, he/she also be given a copy. You may wish to execute this document formally before a notary public, but notarization is not required by the RCC.